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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/374,338	08/13/1999	MICHAEL J. HELLER	241/172	3614

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EXAMINER

FRIEND, TOMAS H F

ART UNIT

PAPER NUMBER

1639

DATE MAILED: 01/13/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/374,338

Applicant(s)

HELLER ET AL.

Examiner

Tomas Friend

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 09 August 2001.
- 2a) ☐ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-137 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☐ Claim(s) _____ is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☒ Claim(s) 1-137 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

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Detailed Action

Change of Art Unit Designation

Please note: The Art Unit location of this application in the PTO has changed from Art Unit 1627 to Art Unit 1639. To aid in matching papers to this application, all further correspondence regarding this application should be directed to **Group Art Unit 1639**.

Status of the Application

Receipt is acknowledged of preliminary amendment with disk on 09 August 2001 (Paper No. 18), and a supplemental I.D.S. on 16 April 2002 (Paper No. 19).

Status of the Claims

Claims 1-137 are pending in the present application and are subject to restriction and election of species requirements.

Restriction

Restriction to one of the following inventions is required under 35 U.S.C. 121:

- I. Claims 1-40, drawn to an array based molecular descriptor device for interacting with a specific ligand molecule or structure, classified in class 435, digest 22.
- II. Claims 41-54, drawn to a method for the combinatorial selection of supermolecular complexes on an electric array based device, classified in class 435 and one of digests 2-21, depending on the compositions of the complexes.
- III. Claims 55-60, drawn to a method for drug discovery, classified in class 435 and one of digests 2-21, depending on the compositions of the complexes.

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- IV. Claims 61-65, drawn to a method for evolving an improved molecular descriptor array, classified in class 435 and one of digests 2-21, depending on the compositions of the complexes.
- V. Claims 66-71, drawn to a method for the formation of supermolecular complexes on an array, classified in class 435 and one of digests 46-51, depending on the compositions of the complexes.
- VI. Claims 72-76, drawn to a method for the formation of supermolecular complexes, classified in class 435 and one of digests 46-51, depending on the compositions of the complexes.
- VII. Claims 77-82, drawn to a method for the formation of supermolecular structures on an electric microarray, classified in class 435 and one of digests 46-51, depending on the compositions of the complexes.
- VIII. Claims 83-135, drawn to a device for the formation and detection of supermolecular complexes, classified in class 435, digest 45.
- IX. Claims 136 and 137, drawn to a method for forming supramolecular structures in an exponential library by aggregation of sublibraries, classified in class 435, digest 49.

The inventions are distinct, each from the other because:

Inventions II-IV and Inventions I are related as process and apparatus for its practice.

The inventions are distinct if it can be shown that either: (1) the process as claimed can be practiced by another materially different apparatus or by hand, or (2) the apparatus as claimed can be used to practice another and materially different process. (MPEP § 806.05(e)). In this case the selection, determining, discovery, and evolving methods (i.e. different processes) of Inventions II-IV can all be practiced using the device (apparatus) of Invention I.

Inventions V-VII and IX and Invention I are related as process of making and product made. The inventions are distinct if either or both of the following can be shown: (1) that the process as claimed can be used to make other and materially different product or (2) that the product as claimed can be made by another and materially different process (MPEP § 806.05(f)).

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In the instant case the methods for forming/formation of supermolecular structures/complexes of Inventions V-VII and IX can all be used to make the device of Invention I.

Inventions VIII and IX are related as apparatus and product made. The inventions in this relationship are distinct if either or both of the following can be shown: (1) that the apparatus as claimed is not an obvious apparatus for making the product and the apparatus can be used for making a different product or (2) that the product as claimed can be made by another and materially different apparatus (MPEP § 806.05(g)). In this case the device of Invention I can be made using the device of Invention VIII and the device of Invention VIII can also be used to make arrays other than supermolecular arrays.

Inventions II-VII and IX are different and patentably distinct methods because they involve different method steps, starting materials, reagents, and/or reaction conditions and/or produce different products or results. For example, the methods of Inventions II-IV are methods for combinatorial selection, determining, discovery, and evolving (i.e. screening and/or analytical methods) while the methods of Inventions V-VII and IX are methods for the formation of supermolecular complexes and/or structures. The methods of Inventions II-IV have different methods steps and are performed to achieve different results. The methods of Inventions V-VII and IX require different materials and/or involve different method steps.

Inventions V-VII and IX and Invention VIII are related as process and apparatus for its practice. The inventions are distinct if it can be shown that either: (1) the process as claimed can be practiced by another materially different apparatus or by hand, or (2) the apparatus as claimed can be used to practice another and materially different process. (MPEP § 806.05(e)). In this case the device (apparatus) of Invention VIII can be used in the methods of formation of supermolecular complexes/structures of Inventions V-VII and IX (different processes).

Inventions VIII and Inventions II-IV are different and patentably distinct inventions. The device of Invention VIII is not used in the methods of Inventions II-IV nor is the device of Invention VIII made using the methods of Inventions II-IV.

Because these inventions are distinct for the reasons given above and

a. have acquired a separate status in the art as shown by their different classification ;

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- b. have different and separately burdensome: manual and/or computer: structure, name and bibliographical searches; and
- c. have divergent subject matter, restriction for examination purposes as indicated is proper.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a diligently filed petition under 37 CFR 1.48(b) and by the fee required under CFR 1.17(h).

Election of Species

This application contains claims directed to the patentably distinct species of the claimed invention.

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable.

If applicants elect Invention I, applicants are required to elect species for each of the following A-D:

- A. Ultimate species of specific ligand molecule or structure (i.e. the structure of the molecule or specific structure such as a specific cell type, specific organelle, etc.),
- B. Species of ligand binding component such as a peptide, enzyme, antibody, amino acid, metal chelator, drug, metabolite metal ion, or a specific combination (a generic such as small molecule or large molecule would be considered non-responsive),
- ~~C. Ultimate species of first programmable pairing component (i.e. structure), AND~~
- D. Ultimate species of second programmable pairing component (i.e. structure).

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If applicants elect Invention II, applicants are required to elect species for each of the following A-E:

- A. Ultimate species of common capture programmable pairing component (i.e. exact structure),
- B. Species capture intermolecular ligand binding structure,
- C. Species of ligand binding component,
- D. Species of complementary intermolecular ligand binding structures (including the structural connectivity between a programmable pairing component and ligand binding component), AND
- E. Ultimate species of specific ligand molecule or structure (i.e. the structure of the molecule or specific structure such as a specific cell type, specific organelle, etc.).

If applicants elect Invention III, applicants are required to elect species for each of the following A-E:

- A. Species of expected biological response,
- B. Ultimate species of known substrate (i.e. chemical structure) and whether or not it is a drug,
- C. Species of response profile,
- D. Ultimate species of test substrate (i.e. chemical structure) or species of related Compounds, AND,
- E. Species of molecular descriptor array (i.e. composition including functionally cooperative relationships).

If applicants elect Invention IV, applicants are required to elect species for each of the following A-C:

-
- A. Ultimate species of specific ligand molecule or structure (i.e. the structure of the molecule or specific structure such as a specific cell type, specific organelle, etc.),
 - B. Species of molecular descriptor array (i.e. the composition of the array including functionally cooperative relationships), AND
 - C. Species of response.

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If applicants elect Invention V, applicants are required to elect species for each of the following A-F:

- A. Ultimate species of specific ligand molecule or structure (i.e. the structure of the molecule or specific structure such as a specific cell type, specific organelle, etc.),
- B. Ultimate species (chemical structure) of capture programmable pairing component,
- C. Species of ligand binding components (including the structural connectivity between a programmable pairing component and ligand binding component),
- D. Species of intermolecular binding components a,
- E. Species of intermolecular binding components b, AND
- F. Species of pairing components.

If applicants elect Invention VI, applicants are required to elect species for each of the following A-F:

- A. Ultimate species of specific ligand molecule or structure (i.e. the structure of the molecule or specific structure such as a specific cell type, specific organelle, etc.),
- B. Species of intermolecular ligand binding structure a,
- C. Species of intermolecular ligand binding structure b,
- D. Species of array of capture intermolecular ligand binding structures (i.e. composition),
- E. Ultimate species of common capture programmable pairing component, AND,
- F. Species of ligand binding component (including the structural connectivity between a programmable pairing component and ligand binding component).

If applicants elect Invention VII, applicants are required to elect species for each of the following A-F:

- A. Species (structure(s)) of capture intermolecular ligand binding structure(s),
- B. Ultimate species (i.e. exact structure) of common programmable pairing component,
- C. Species of ligand binding component (including the structural connectivity between a programmable pairing component and ligand binding component),

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- D. Species of intermolecular ligand binding structure a,
- E. Species of intermolecular ligand binding structure b, AND
- F. Ultimate species of specific ligand molecule or structure (i.e. the structure of the molecule or specific structure such as a specific cell type, specific organelle, etc.).

If applicants elect Invention VIII, applicants are required to elect species for each of the following A-E:

- A. Species of molecular recognition system (i.e. composition of the system including species of molecules present in any pairing system and structural connectivities between components),
- B. Species of first molecular recognition component,
- C. Species of second molecular recognition component,
- D. Species of separate molecular species bound to the molecular recognition system, (e.g., peptide, antibody, antibody fragment), AND
- E. Species of third structure.

If applicants elect Invention IX, applicants are required to elect species for each of the following A and B:

- A. Species of supramolecular structures (i.e. compositions and structural relationships between components), AND
- B. Species of components subjected to electronic stringency.

The species are distinct, each from the other, because they have different structures with different chemical, physical, and/or pharmacological properties. Therefore, different issues of enablement and patentability apply to each species and each species represents patentably distinct subject matter.

Applicants are advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

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Upon the allowance of a generic claim, applicants will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

Should applicants traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to **Tomas Friend**, telephone number (703) 308-4548. The examiner's schedule is normally four, ten-hour days per week that includes Saturdays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Andrew Wang can be reached on (703) 306-3217. The fax phone number for the organization where this application or proceeding is assigned is (703) 308-2742.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist at (703) 308-1235.

Tomas Friend, Ph.D.
07 January 2003



ANDREW WANG
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600